Approved for use through 04/30/2003

nuu & 1 200,3

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF CO

eduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB pont

•	Application Number	09/896,812	distil
TRANSMITTAL	Filing Date	June 29, 2001	XISIE
FORM	First Named Inventor	Madden, Thomas D.	07
(to be used for all correspondence after initial filing)	Art Unit	1615	
	Examiner Name	Gollamudi S. Kishore	

Total Number of Pages in This Submission Attorney Docket Number 016303-008030US ENCLOSURES (Check all that apply) After Allowance Communication to Group Fee Transmittal Form ☐ Drawing(s) Appeal Communication to Board of Appeals Licensing-related Papers Fee Attached and Interferences Petition Appeal Communication to Group (Appeal Amendment/Reply Notice, Brief, Reply Brief) Petition to Convert to a Proprietary Information After Final Provisional Application Power of Attorney, Revocation Affidavits/declaration(s) Status Letter Change of Correspondence Address Terminal Disclaimer Other Enclosure(s) Extension of Time Request (please identify below): Request for Refund Return Postcard; Express Abandonment Request Cited References AA-AW CD. Number of CD(s) Information Disclosure Statement The Commissioner is authorized to charge any additional fees to Deposit Certified Copy of Priority Account 20-1430. Remarks Document(s) Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Townsend and Townsend and Crew LLP Firm Reg. No. 39,381 Joseph R. Snyder Individual Signature Date 2003

## CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name Jose Luna August 14, 2003 Date Signature

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Attorney Docket No.: 016303000

**TECH CENTER 1600/2900** 

ommissioner for Patents D. Box 1450 exandria, VA 22313-1450

TOWNSEND and TOWNSEND and CREW LLP

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Thomas D. Madden, et al.

Application No.: 09/896,812

Filed: June 29, 2001

For: LIPOSOMAL ANTINEOPLASTIC

DRUGS AND USES THEREOF

Examiner: Gollamudi S. Kishore

Art Unit: 1615

INFORMATION DISCLOSURE

STATEMENT UNDER 37 CFR §1.97 and

§1.98

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of the references are enclosed.

It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no

09896812

Thomas D. Madden, et al. Application No.: 09/896,812

Page 2

representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

This IDS is being filed before the mailing date of the final Office Action or Notice of Allowance.

Please charge the IDS fee of \$180 to Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

Joseph R. Snyder Reg. No. 39,381

TOWNSEND and TOWNSEND and CREW LLP Two Embarcadero Center, 8<sup>th</sup> Floor San Francisco, California 94111-3834 Tel: 925-472-5000

Tel: 925-472-5000 Fax: 925-472-8895

JS:ath

60015659 v1

## AUG 2 1 2003

3

Page

**TECH CENTER 1600/2900** 

PTO/SB/08A (04-03) Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Substitute for form 1449/PTO Complete if Kn wn 09/896,812 Application Number INFORMATION DISCLOSURE Filing Date June 29, 2001 STATEMENT BY APPLICANT Madden, Thomas D. **First Named Inventor** Art Unit 1615 (use as many sheets as necessary) **Examiner Name** Gollamudi S. Kishore 016303-008030US

Attorney Docket Number

			U.S. PATENT D	OCUMENTS	
		Document Number		·	D. Oak was kinne Whee
Examiner	Cite No.1	Number Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	US-5,023,087	06/11/1991	Yau-Young	
	AB	US-5,552,156	09/03/1996	Burke	
	AC	US-5,837,282	11/17/1998	Fenske et al.	

			Foreign Patent Docum	ent		Name of Patentee or	Pages, Columns, Lines,	
Examiner Initials*	Cite No. <sup>1</sup>	Country Code	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Applicant of Cited  Document	Where Relevant Passages or Relevant Figures Appear	Τ'
	AD	PCT	WO 95/08986	A1	04/06/1995	SmithKline Beecham Corporation		
	AE	PCT	WO 98/17256	A1	04/30/1998	Kirpotin, Dmitri		
	AF	PCT	WO 99/51202	A2	10/14/1999	Sequus Pharmaceuticals, Inc.		
	AG	PCT	WO 00/23052	A1	04/27/2000	Alza Corporation		

Examiner Signature	Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Kind Codes of U.S. Patent Documents at <a href="www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PINE TANCO

TECH CENTER 1600,2000

PTO/SB/08B (04-03) Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE der the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Complete if Known Substitute for form 1449/PTO **Application Number** 09/896,812 INFORMATION DISCLOSURE **Filing Date** June 29, 2001 STATEMENT BY APPLICANT Madden, Thomas D. First Named Inventor 1615 Art Unit (use as many sheets as necessary) Gollamudi S. Kishore **Examiner Name** 016303-008030US Attorney Docket Number Page of 3

		NON PATENT LITERATURE DOCUMENTS	,
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	- AH	BURRIS III et al., "Activity of topotecan, a new topoisomerase I inhibitor, against human tumor colony-forming units in vitro," Journal of the National Cancer Institute 84(23):1816-1820 (1992)	
	· Al	CLEMENTS et al., "Antiangiogenic potential of camptothecin and topotecan," Cancer Chemother. Pharmacol. 44:411-416 (1999)	
	· AJ	EMERSON et al., "In vivo antitumor activity of two new seven-substituted water-soluble camtothecin analogues," Cancer Research 55:603-609 (1995)	
	AK	ERICKSON-MILLER et al., "Differential toxicity of camptothecin, topotecan and 9-aminocamptothecin to human, canine, and murine myeloid progenitors (CFU-GM) in vitro," Cancer Chemother. Pharmacol. 39:467-472 (1997)	
	- AL	GROCHOW et al., "Pharmacokinetics and pharmacodymanics of topotecan in patients with advanced cancer," Drug Metabolism and Disposition 20(5):706-713 (1992)	
	, AM	HARDMAN et al., "Efficacy of treatment of colon, lung and breast human carcinoma xenografts with: Doxorubicin, cisplatin, irinotecan or topotecan," Anticancer Research 19:2269-2274 (1999)	
	· AN	HSIANG et al., "Identification of mammalian DNA topoisomerase I as an intracellular target of the anticancer drug camptothecin," Cancer Research 48:1722-1726 (1988)	
	· AO	MADDEN et al., "The accumulation of drugs within large unilamellar vesicles exhibiting a proton gradient; a survey," Chemistry and Physics of Lipids 53:37-46 (1990)	
	` AP	MADDEN et al., "Encapsulation of topotecan in lipid-based carrier systems. Evaluation of drug stability and plasma elimination in a murine model, and comparison of antitumor efficacy against murine L1210 and B16 tumors," Proc. of ASCO, 17:abstract #754 (1998)	
	AQ	MAYER et al., "Characterization of liposomal systems containing doxorubicin entrapped in response to pH gradients," Biochimica et Biophysica Acta 1025:143-151 (1990)	
	AR	McCABE et al., "Comparative activity of oral and parenteral topotecan in murine tumor models: Efficacy of oral topotecan," Cancer Investigation 12(3):308-313 (1994)	
	AS	O'LEARY et al., "Antiangiogenic effects of camptothecin analogues 9-amino-20(S)-camptothecin, topotecan, and CPT-11 studied in the mouse cornea model," Clinical Cancer Research 5:181-187 (1999)	
	- AT	ORMROD and SPENCER, "Topotecan: A review of its efficacy in small cell lung cancer," <i>Drugs</i> 58(3):533-551 (1999)	
	. AU	TARDI et al., "Liposomal encapsulation of topotecan enhances anticancer efficacy in murine and human xenograft models," Cancer Research 60:3389-3393 (2000)	

Examiner	-	Date	
Signature		Considered	 

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

AUG 1 8 2003

## AUG 2 1 2003

AUG 1 8.2003

PTO/SB/08B (04-03)

TECH CENTER 1600/2900.

PTO/SB/08B (04-03)

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449/PTO		Complete if Known
	Application Number	09/896,812
INFORMATION DISCLOSURE	Filing Date	June 29, 2001
STATEMENT BY APPLICANT	First Named Inventor	Madden, Thomas D.
	Art Unit	1615
(use as many sheets as necessary)	Examiner Name	Gollamudi S. Kishore
Page 3 of 3	Attorney Docket Number	016303-008030US

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	, AV	THOMPSON et al., "Animal models for studying the action of topoisomerase I targeted drugs," Biochimica et Biophysica Acta 1400:301-319 (1998)	
	, AW	WALL et al., "Plant antitumor agents. I. The isolation and structure of camptothecin, a novel alkaloidal leukemia and tumor inhibitor from Camptotheca acuminata," Journal of the American Chemical Society 88(16):3888-3890 (1966)	

Examiner	Date
Examine	Date
Signature	Considered
Cignataro	 

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation in not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.